

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL NO. 1456
LITIGATION)	Civil Action No. 01-12257-PBS
)		
THIS DOCUMENT RELATES TO)	Hon. Patti B. Saris
ALL CLASS ACTIONS)	Chief Magistrate Judge Marianne B. Bowler
)		

THE JOHNSON & JOHNSON DEFENDANTS' RESPONSE TO PLAINTIFFS' OBJECTIONS TO CHIEF MAGISTRATE JUDGE BOWLER'S RULINGS REQUIRING PLAINTIFFS TO ANSWER REQUESTS FOR ADMISSION AND INTERROGATORIES CONCERNING PROCRIT® AND REMICADE®

The J&J Defendants respectfully submit this response to plaintiffs' objections to Chief Magistrate Judge Marianne B. Bowler's rulings requiring plaintiffs to respond under oath to the J&J Defendants' Requests for Admission ("RFAs") and Interrogatories regarding Procrit® and Remicade®. These two medicines, which are sold respectively by Ortho Biotech Products LP and Centocor, Inc., are the only J&J company drugs remaining in the case. Plaintiffs' objections to the Magistrate Judge's rulings are ill-founded, and appear to be designed to delay the just and speedy resolution of these proceedings. (See Declaration of Andrew D. Schau dated December 6, 2005, submitted herewith.)

The Standard of Review

"Nondispositive" discovery rulings, such as those at issue here, may be set aside only where they are "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a); *see Phinney v. Wentworth Douglas Hosp.*, 199 F.3d 1, 5 (1st Cir. 1999) (order imposing discovery sanctions considered nondispositive); 12 Charles Alan Wright et al., *Federal Practice and Procedure*

§ 3068.2, at 341-43 (2d ed. 1997) (“Disputes about the handling of discovery . . . should ordinarily be viewed as nondispositive.”); *compare In re Administrative Subpoena Blue Cross Blue Shield of Massachusetts, Inc.*, No. 05-10041-PBS, 2005 WL 3178175, at *1 (D. Mass. Nov. 18, 2005) (ruling on motion to enforce subpoena is dispositive where it is “[t]he only matter for this Court to decide”).

Chief Magistrate Judge Bowler carefully reviewed each RFA and Interrogatory. She listened attentively to oral argument addressed to each individual request. (See Pl. Ex. A, 11/09/05 Tr. at 8.) Plaintiffs had every opportunity to convince her that their refusal to respond to the requests was proper, but she was not persuaded. She properly ruled that plaintiffs’ blanket objections were improper. She ordered plaintiffs to admit or deny the RFAs, or explain under oath why they cannot do so. She ruled that plaintiffs should answer the Interrogatories, or state under oath that they cannot answer the interrogatories because they do not know the answers.

These rulings are not “clearly erroneous” and they are certainly not “contrary to law.” The RFAs and Interrogatories served by the J&J Defendants are straight forward, and the information they seek is highly probative of the parties’ claims and defenses. Plaintiffs should answer them, under oath, as they have been ordered to do.¹

Discussion and Argument

After years of exhaustive and oft times grueling discovery, the J&J Defendants served RFAs and Interrogatories with respect to Procrit and Remicade. These requests, which were made at the tail end of the discovery period, were a long time coming. The J&J Defendants have maintained from the beginning that they did nothing wrong, and that plaintiffs’ claim that

¹ Plaintiffs did not seek, and were not granted, a stay of their obligation to comply with Chief Magistrate Judge Bowler’s rulings. The filing of objections does not relieve a party of its obligation to respond. See Rule 2(b) of the Local Rules of the District of Massachusetts. Plaintiffs are currently in default, and they have not said whether they intend to comply with the rulings. See Schau Decl., ¶¶ 7-11.

they somehow defrauded payers is utterly baseless. The J&J Defendants expect to move for summary judgment.

In anticipation of that motion, the J&J Defendants served RFAs and Interrogatories that were designed to narrow the issues and confirm facts that are firmly established in the discovery record.² For example, plaintiffs were asked to admit that the published AWP for Remicade has always been 130% of its published WAC (Pl. Ex. C, RFA 2), and that Centocor never paid rebates to physicians or to PBMs. (*Id.*, RFAs 3 and 4). Plaintiffs were also asked to identify the various benchmark and other prices (AWPs, WACs, ASPs, etc.) alleged to be fraudulent.

The J&J Defendants propounded these requests in order to avoid the burden and expense of having to establish facts on summary judgment as to which there is no genuine dispute. Having taken full and complete discovery of the J&J Defendants, plaintiffs are certainly capable of providing meaningful responses; they simply do not want to. Their refusal to respond is inexcusable. It is time that plaintiffs stopped posturing, faced the facts with respect to the J&J Defendants, and cooperated with the J&J Defendants' effort to move this litigation forward to the next stage.

Plaintiffs' reluctance to respond to the J&J Defendants' discovery requests is improper, but predictable. As plaintiffs surely recognized when they received the RFAs and Interrogatories, the requests were carefully crafted so that candid and truthful responses could be used to establish some of the key arguments that the J&J Defendants will use to support their motion for summary judgment. For example, plaintiffs have long known from their discovery

² The accepted purpose of requests for admission is to narrow the issues in dispute. The Advisory Committee Notes to Rule 36 explicitly confirm this, stating that the purpose of requests for admissions is "first, to facilitate proof with respect to issues that cannot be eliminated from the case, and secondly, to narrow the issues by eliminating those that can be." Fed. R. Civ. P. 36 Advisory Committee Notes (1970 amendment).

relating to Remicade that Centocor never paid rebates to physicians.³ This fact flatly contradicts plaintiffs' allegation that physicians were given "secret" price concessions in exchange for administering Remicade instead of some other therapy. Thus, rather than admit that Centocor did not pay rebates to physicians, plaintiffs instead objected that the RFA cannot be answered because the term "rebates" is "vague and ambiguous." (Pl. Ex. E, RFAs 3-4.)

Plaintiffs' objection is a complete fabrication. Plaintiffs surely know what a "rebate" is. They used the term repeatedly in their Third Amended Master Consolidated Complaint. It is also used countless times in plaintiffs' expert reports on class certification. It is simply inconceivable that plaintiffs cannot admit that Centocor did not pay rebates to physicians RFAs because they do not know what a rebate is.

Plaintiffs' objections to the J&J Defendants' other requests are equally groundless. For example, plaintiffs' entire case hinges on the allegation that the defendants' published WAC and AWP figures that are fraudulent and inflated. But when plaintiffs were asked by the J&J Defendants to identify the specific WAC and AWP figures alleged to be fraudulent, plaintiffs responded weakly that they should not have to do so because this information is "within the J&J Defendants' possession." (Pl. Ex. D, Interrogatory 4; P. Ex. E, Interrogatory 9.) They further state that, if the J&J Defendants will give them "the exact data" that forms the basis of the RFA, they will "consider" providing an answer. (*Id.*)

These objections are galling to say the least. Plaintiffs have represented time and again that the J&J Defendants' WAC and AWP figures are fraudulent. Surely at the end of the discovery period they are able to say what those figures are. Indeed, they ought to have had this

³ Despite knowing that Centocor did not pay rebates to physicians, plaintiffs' counsel asked defendants' tutorial expert at the hearing on December 7, 2004 whether he was aware Centocor paid physicians rebates on Remicade of more than 40%. Counsel surely knew when he asked the question that the premise of the question was completely false. (See Declaration of John Hoffman, attached to the Schau Declaration as Ex. 2.)

information in hand before bringing this case. If plaintiffs do not know the allegedly fraudulent WAC and AWP figures for Procrit and Remicade, they should admit their lack of knowledge under oath. That admission will speak volumes when the J&J Defendants file their motion for summary judgment.

Another bedrock feature of plaintiffs' case is their assertion that payers pay too much to reimburse for defendants' drugs because they are prevented from knowing the providers' net acquisition price. This core allegation has been described by the Court as follows:

defendants (or wholesalers) sell a drug to retailers at a *net* price often significantly below the expected "AWP minus 16% to 33%" threshold by utilizing hidden discounts, off-invoice rebates, free samples, education grants, and other promotional means that are not reflected in the list price.

In re Pharm. Indust. Average Wholesale Price Litig., 230 F.R.D. 61, 69 (D. Mass. 2005) (emphasis in original).

According to plaintiffs, this difference between net reimbursement cost and the net acquisition cost permits providers to pocket a "spread," which defendants allegedly manipulate in order to induce sales and increase their market share. As the Court noted, plaintiffs are claiming that:

manufacturers actually sell drugs to providers like pharmacies and doctors at prices far below AWP and WAC. This creates a "spread" between the price healthcare providers pay to acquire drugs from wholesalers or manufacturers (the average acquisition cost, "AAC") and the reimbursement rate paid by TPPs, the government, and consumers making co-insurance payments or paying the entire cost of a drug.

Id. at 68.

Several of the J&J Defendants' RFAs and Interrogatories focus on these basic allegations. Plaintiffs were thus asked to identify the providers' "net acquisition cost," and the payers' "net reimbursement cost." (Pl. Ex. B, RFA 5; Pl. Ex. C, RFA 11.) These terms were

defined in the discovery requests, as plaintiffs themselves have defined them, as the selling and reimbursement prices “net of any rebates or other price adjustments.” (E.g., Pl. Exs. B & C at 2-3.) In the case of Remicade, plaintiffs were asked to admit that the difference between net acquisition cost and net reimbursement cost is *less than* the difference between WAC and AWP. (Pl. Ex. C, RFA 8.) In the case of Procrit, they were asked to admit this difference is *less than* the difference between ASP and AWP. (Pl. Ex. B, RFA 3.)

Plaintiffs presumably realized that providing truthful responses to these requests would jeopardize their case against the J&J Defendants. Answering the Remicade RFAs, for example, would show that the “spread” between acquisition and reimbursement cost was less than the *published* difference between WAC and AWP (*i.e.*, less than 30%), negating any possible finding that Centocor defrauded class members who reimbursed for Remicade.

Plaintiffs must also have realized that giving truthful responses to the Procrit RFAs would bolster another important defense argument, *viz*: that payers *benefit* from the discounts they receive from manufacturers because they *lower* the payers’ net reimbursement costs. Including these discounts in “the spread,” as Dr. Hartman does, is completely nonsensical, because it punishes manufacturers for reducing reimbursement costs. The Procrit RFA documents this fact in the form of an admission. Plaintiffs’ should not be permitted to avoid answering it.

In their objections to Chief Magistrate Judge Bowler’s rulings, plaintiffs made the additional argument that they should not have to answer requests concerning net acquisition cost because the price providers pay to acquire drugs “*is not relevant to Plaintiffs’ theory.*” (Memo. at 4 (emphasis added).) In fact, plaintiffs admitted that they “don’t know” the providers’ net acquisition cost because they “have no idea what the wholesalers’ mark-up is.” (*Id.* at 14.) They

also admitted that they could not calculate the payers' net reimbursement costs because reimbursement "data from the entire class" is "not available" to plaintiffs. (Pl. Ex. A at 13.)

It is nothing less than astonishing that plaintiffs are proceeding at this stage of the case without knowing how much the providers' pay to acquire Procrit and Remicade, or how much class members pay to reimburse for these medicines. It is even more astonishing, as plaintiffs also admitted, that they "have not attempted to figure it out." (*Id.*) This may be because they no longer believe that acquisition cost and reimbursement costs are "relevant" to their case. But whatever the changes in plaintiffs' theories, these prices certainly remain relevant to the J&J Defendants' defense.

The fact that plaintiffs claim not to know these prices is no excuse for not responding to the J&J Defendants' requests. Thus, while it is true that plaintiffs cannot be made to swear to numbers they do not know, it is equally true that the J&J Defendants are entitled to a written response from plaintiffs stating, under oath, that they do not even know what providers pay to acquire Remicade and Procrit, or how much the class members they represent pay to reimburse for these medicines. That is all Chief Magistrate Judge Bowler required of plaintiffs, and there is no reason on earth plaintiffs cannot comply with her order. (*See* Pl. Ex. A at 15-16.) When they comply, their admissions will be highly probative to the Court's consideration of the J&J Defendants' motion for summary judgment, and they will be no less probative if the Court is ever required to make a reasoned assessment of plaintiffs' damages claim.

Conclusion

As is her practice, Chief Magistrate Judge Bowler heard argument on each of plaintiffs' objections and ruled in every case that plaintiffs should admit or deny the RFAs, provide answers to the Interrogatories, or state under oath that they cannot respond because they do not know the answers. Her rulings are not clearly erroneous or contrary to law. Plaintiffs' objections should be overruled.

Dated: December 6, 2005

Respectfully submitted,

/s/ Andrew D. Schau

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CERTIFICATE OF SERVICE

I certify that on December 6, 2005, a true and correct copy of the forgoing The Johnson & Johnson Defendants' Response to Plaintiffs' Objections to Chief Magistrate Judge Bowler's Ruling Requiring Plaintiffs to Answer Requests for Admission and Interrogatories Concerning Procrit® and Remicade® was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Lexis/Nexis File & Serve for posting and notification to all parties.

/s/ Andrew D. Schau
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